



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/981,998	05/11/98	PULST	202-00019120

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HM12/0921

EXAMINER
ENEWOLD, J

ART UNIT	PAPER NUMBER
1655	12

DATE MAILED: 09/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION

The effective filing date of a U.S. application may be determined as follows:

- (A) If the application is a continuation or divisional of one or more earlier U.S. applications and if the requirements of 35 U.S.C. 120 have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.
- (B) If the application is a continuation-in-part of an earlier U.S. application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application. Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application.
- (C) If the application claims foreign priority under 35 U.S.C. 119(a)-(d), the effective filing date is the filing date of the U.S. application, unless situation **>(A) or (B)< as set forth above applies. The filing date of the foreign priority document is not the effective filing date, although the filing date of the foreign priority document may be used to overcome certain references. See MPEP § 706.02(b) and § 2136.05.
- (D) If the application is entitled to priority under 35 U.S.C. 119(e) from a provisional application, the effective filing date is the filing date of the provisional application.

See MPEP § 1893.03(b) for determining the effective filing date of an application filed under 35 U.S.C. 371. See MPEP § 201.11(a) and § 1895 for determining the effective filing date of a continuation, divisional, or continuation-in-part of a PCT application designating the U.S. See also MPEP § 1895.01 and § 1896 which discuss differences between applications filed under 35 U.S.C. 111(a) and 35 U.S.C. 371.

Office Action Summary

Application No.
08/981,998

Applicant(s)

Pulst

Examiner
Jeanine Enewold

Group Art Unit
1655



☒ Responsive to communication(s) filed on Jul 19, 1999.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-43 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-43 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, 27-29,37,40,43, drawn to primers, vector, host cell, antisense oligonucleotides, kits and a method to detect SCA2 nucleic acid.

Group II, claim(s) 16-23, drawn to SCA2 polypeptide.

Group III, claim(s) 24-26, 30, 39, drawn to an antibody and a method for detecting the presence of human SCA2 polypeptide with an antibody.

Group IV, claim(s)31-36, drawn to a transgenic animal.

Group V, claim(s) 38, drawn to a method for identifying compounds which bind to SCA2.

Group VI, claim(s) 41 and 42, drawn to a method of diagnosing spinocerebellar ataxia type 2 using the SCA1 nucleic acid.

2. The inventions listed as Groups I, II, III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

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A) The inventions of Groups I, II, III, and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The transgenic animal of Group IV is a composition made up of structurally and functionally complex biological systems. Furthermore, the products of Groups I, II, III, and IV can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group II can be used to make fusion protein with an enzymatic function, while transgenic animals can be used to express different proteins other than SCA2. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, III, and IV are patentably distinct from each other.

B) Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product.

C) The inventions of Groups III and V are drawn to distinct methods having different objectives, different reagents and different steps. The method of Group III for detecting the SCA2 polypeptide in an immunoassay using an antibody while the method of Group V is a method for identifying compounds which are ligands for the SCA2 receptor by mixing the SCA2 polypeptide with a test compound. These methods have unrelated objectives and different steps making them distinct methods.

D) Group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case the nucleic acid of Group I can be used in a materially different method such as detection and localization of the native receptor gene, amplification of receptor sequences, and expression of the receptor protein sequence.

E) Groups IV and V, and IV and VI are patentably distinct because the transgenic animal of Group IV is not used in methods for identifying compounds which bind to SCA2 polypeptide of Group V. Additionally, the transgenic animal of Group IV is not used in methods for diagnosing spinocerebellar ataxia type 2 as in group VI. Consequently, these inventions are unobvious applications of the SCA2 gene and polypeptide.

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F) Group I and V are patentably distinct because the nucleic acid of Group I is not used in methods for identifying compounds which bind to SCA2 polypeptides as in Group V and the method of Group V does not rely on the SCA2 nucleic acid of Group I.

G) Groups II and VI, and III and VI are patentably distinct because neither the polypeptide of Group II nor the antibody of Group III are used in the method of diagnosing spinocerebellar ataxia type 2 as in Group VI which uses the nucleic acid. The method of VI does not involve the polypeptide or the antibody for diagnosis of spinocerebellar ataxia 2. Therefore the inventions are patentably distinct.

H) Inventions V and VI are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of V is for identifying compounds which bind SCA2 by mixing a test compound with the SCA2 polypeptide. Alternatively, the method of VI is for diagnosing spinocerebellar ataxia 2 by detecting mutations in the SCA2 nucleic acid. Therefore the methods are distinct over one another.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00 AM to 4:30 PM.

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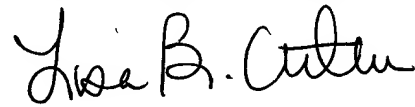
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jeanine Enewold

September 20, 1999



LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800- 1600